



K963320

DEC - 3 1996

510(k) SUMMARY

[As required by 21 CFR 807.92]

1. Submitter and Contact Person

Neil R. Armstrong
Group Regulatory Affairs Manager
TFX Medical Group
Tall Pines Park
Jaffrey NH 03452
Tel: (603) 532 7706
Fax: (603) 532 8211

2. Device Name

Trade Name
TFX Medical Guidewire

Common Name
Guidewire

Classification Name
Wire, Guide, Catheter
74 DQX; 21 CFR 870.1330; Class II medical device

3. Comparison Devices

Teleflex Guidewire -	K850677/B
Teleflex Teflon® Coated Guidewire -	K860258/A
Teleflex Steerable Guidewire -	K871850

Arrow International Inc. -	K914531, K924607, K924438
Argon Medical Corporation -	K841926, K871297
Cook Incorporated -	K901899, K920824, K920891
Guidewire Technologies -	K902152/3
Lake Region Manufacturing -	K770977, K864058, K871882,
	K901224, K914138, K921200,
	K935170, K935198, K941229

4. **Description of Device**

TFX Medical will supply a standard range of guidewires as sterile, packed finished products, and will also supply in bulk to other manufacturer to their specific size requirements (for example: for inclusion in a kit).

The key features of the TFX Medical Guidewire are:

- ☐ Core Wire
- ☐ Ribbon Wire (where fitted)
- ☐ Spring Wire
- ☐ Welds
- ☐ Coating (p.t.f.e. coating or uncoated stainless steel)
- ☐ Tips (available straight and "J" forms, one or two tips)

Guidewires will be manufactured of grade 302/304 stainless steel and be available:

- with and without a ribbon wire
- in fixed and moveable core designs
- uncoated and p.t.f.e. coated
- with straight and "J" formed end(s)
- with and without a length marking

5. **Intended Use**

TFX Medical Guidewires are intended to fit inside a percutaneous catheter for the purpose of directing it through a blood vessel or other natural channel - excluding use in coronary arteries and in the neurovasculature.

6. **Summary of Technological Characteristics**

TFX Medical Guidewire will be made of stainless steel, with fixed or moveable cores, with or without a ribbon wire, with one or two straight or "J" form tips and will be available uncoated and p.t.f.e. coated. All these technical characteristics are the same as the predicate Teleflex Guidewires.

7. **Summary of Performance Data**

Test data in the premarket notification demonstrates TFX Medical Guidewires meeting the requirements of the appropriate parts of British Standard BS 7174: 1990: Part 4.